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Dkt. 50634-BA/JPW/AJM/AAB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Eric Rose, et al.
U.S. Serial No.: ^{10/646,493}~~10/646,593~~ Examiner: J. Russel
Filed : August 21, 2003 Art Unit: 1654
For : METHODS FOR INHIBITING THROMBOSIS IN A
PATIENT WHOSE BLOOD IS SUBJECTED TO
EXTRACORPOREAL CIRCULATION

1185 Avenue of the Americas
New York, New York 10036
October 28, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Sir:

COMMUNICATION IN RESPONSE TO SEPTEMBER 28, 2004 OFFICE ACTION

This Communication is submitted in response to a September 28, 2004 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the September 28, 2004 Office Action is due October 28, 2004. Accordingly, this Communication is being timely filed.

Applicant : Eric Rose, et al.
Serial No.: 10/646,493
Filed : August 21, 2003
Page 2

Restriction Requirement

In the Office Action, the Examiner restricted the pending claims to one of the following allegedly distinct inventions under 35 U.S.C. §121:

- I. Claims 1, 20, 33 and 34, drawn to a method of inhibiting thrombosis or clot formation;
- II. Claim 9, drawn to pharmaceutical compositions comprising Factor IXa compounds;
- III. Claims 13 and 23-28, drawn to an assay to determine the anticoagulant activity of a Factor IXa compound;
- IV. Claim 14, drawn to an assay for evaluating the ability of an agent to inhibit an active site of a Factor IXa compound; and
- V. Claim 19, drawn to an agent capable of inhibiting the active site of Factor IX.

In response, applicants hereby elect, with traverse, Group II, claim 9, drawn to pharmaceutical compositions comprising Factor IXa compounds.

Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. §803, the Examiner must examine the application on

Applicant : Eric Rose, et al.
Serial No.: 10/646,493
Filed : August 21, 2003
Page 3

the merits, even though it includes claims to distinct inventions, if the search and examination can be made without serious burden.

Under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent and distinct, and (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Groups I and III-V would not require a serious burden once the prior art relevant to Group II has been identified. Therefore, there would be no serious burden on the Examiner to examine Groups I-V together in the subject application. Hence, the Examiner must examine these Groups on the merits.

In view of the foregoing, applicants maintain that restriction is not proper under 35 U.S.C. §121 and respectfully request that the Examiner reconsider and withdraw the requirement for restriction.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants'

Applicant : Eric Rose, et al.
Serial No.: 10/646,493
Filed : August 21, 2003
Page 4

undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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